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FDA Approves Generic Versions of ADHD Drug Vyvanse for Ages 6 and up + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By **The Defender Staff**



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FDA Approves Generic Versions of ADHD Drug Vyvanse

The Hill reported:

The Food and Drug Administration (FDA) approved the first generic versions of Vyvanse, a drug used to treat attention-deficit/hyperactivity disorder (ADHD), a decision that comes amid a nationwide shortage of ADHD treatment drugs.

The newly approved medication can treat both ADHD in patients six years and older and binge-eating disorder in adults, the FDA said in an [announcement](#).

The approval comes amid the nationwide shortage of Adderall, a drug commonly prescribed to treat ADHD. The FDA first announced the shortage in October, citing an insufficient supply to meet the growing demand for the drug. Millions of children diagnosed with ADHD are returning to classrooms as the school year kicks off, highlighting the demand for medication that can help them stay focused.

Unexpected demand spikes, manufacturing problems and limited ingredient supplies have all contributed to the shortage. A CDC [analysis](#) earlier this year found prescriptions to treat ADHD surged during the COVID-19 pandemic, as access to drugs expanded with telehealth opportunities.

Should Kids Take Ozempic, Wegovy? The Idea Has Some Experts Worried

U.S. News & World Report reported:

Weight-loss [drugs](#) like Ozempic and Wegovy are surging in popularity, but that doesn't mean they're good for everyone.

Glucagon-like peptide-1 receptor agonists (GLP-1RA) may be dangerous for children, warned researchers at the University of California, Irvine.

Treating childhood [obesity](#) and type 2 diabetes with these injected medications may have unintended and adverse consequences in pediatric patients, the team of clinicians, exercise scientists, pharmaceutical scholars, ethicists and behavioral experts said in their commentary.

While the new class of medication could benefit children with morbid obesity and type 2 diabetes — a problem worsened by COVID pandemic-related shutdowns — the authors suspect overuse and abuse among youth is inevitable.

Researchers Prep Fentanyl, Heroin Vaccines for Human Trials

UM News reported:

Researchers at the University of Montana and their partners are nearing human trials for vaccines to prevent fentanyl and heroin drug overdoses. The vaccines would protect people struggling with drug addiction or those at risk of accidental overdose. According to the National Institutes of Health, more than 106,000 U.S. drug overdose deaths were reported in 2021. Of those, 71,000 can be attributed to synthetic [opioids](#) like fentanyl.

Researcher Jay Evans directs the UM Center for Translational Medicine, which is working on the vaccines. He also is a co-founder of Inimmune, the corporate partner charged with scaling up the vaccine components for manufacture. Inimmune is based in MonTEC, UM's Missoula-based business incubator.

“We anticipate testing our vaccines in humans in early 2024,” Dr. Evans said. “The [first vaccine](#) will target heroin, followed shortly thereafter with a fentanyl vaccine in Phase I [clinical trials](#). Once we establish safety and early efficacy in these first clinical trials, we hope to advance a combined multivalent vaccine targeting both heroin and fentanyl.”

The UM team contributes a patented adjuvant called INI-4001 to the vaccine cocktails. Adjuvants are substances that boost the effectiveness of vaccines.

CEPI Announces New Funding for ‘Disease X’ Vaccine

CIDRAP reported:

The Coalition for Epidemic Preparedness Innovations (CEPI) and the University of Oxford have committed \$80 million to the development of a vaccine targeting “Disease X,” or unknown pathogens with the potential to cause [pandemics](#).

The money will be used to work on vaccine prototypes against viral families most at risk for becoming pathogens that threaten human health at the pandemic scale.

“This is a ground-breaking commitment from CEPI to provide momentum that will drive the critical research that we need to be better prepared for future pandemics,” said Sir Andrew Pollard, Ph.D., director of the Oxford Vaccine Group, in a CEPI [press release](#). “Building on our extensive experience in vaccine development over the past 30 years and world-leading response to COVID-19 with the Oxford-AstraZeneca vaccine, we will strive with CEPI to secure the safety of future generations against the ongoing threats from the microbial world.”

CEPI cited the example of COVID-19, climate change, and globalization as signs that an outbreak from Disease X is inevitable, and the world must be prepared to react swiftly with vaccination. CEPI has previously stated that the goal is to develop vaccines against an emerging pathogen within 100 days.

Biden’s NIH Pick Gives Elizabeth Warren a Major Concession

Politico reported:

President Joe Biden's pick to run the [National Institutes of Health](#) has agreed to a pair of major ethics demands made by Sen. Elizabeth Warren to help jumpstart her stalled candidacy for the top medical research job.

Monica Bertagnolli, who was nominated more than three months ago, pledged to not seek employment or compensation from any of the world's largest pharmaceutical companies for four years after she leaves government, according to a letter sent to the Massachusetts Democrat and obtained by POLITICO.

The restriction applies to all drug firms with annual revenues of \$10 billion or more and includes a prohibition on joining the boards of directors for those companies. Bertagnolli also agreed to recuse herself for four years from NIH decisions related to companies with which she's had prior relationships, up from the standard two-year recusal period.

But Bertagnolli is still mired in a separate standoff with Sen. Bernie Sanders (I-Vt.) that continues to block her path to the NIH job, with no resolution in sight.

Sanders, who chairs the Senate committee responsible for vetting Bertagnolli's candidacy, is denying her a [confirmation hearing](#) over demands that the White House take greater unilateral action to cut [drug](#) prices. The senator has vowed to oppose all of the administration's health nominees until those demands are met, even if it means forcing agencies like the NIH to go without a permanent leader.

EU Regulators Back Pfizer’s Updated Vaccine for Dominant Omicron Subvariant

Reuters reported:

EU regulators have recommended authorizing an updated [COVID-19](#) vaccine from [Pfizer](#) (PFE.N) and its German partner BioNTech ([22UAY.DE](#)) which targets the dominant XBB.1.5 variant of [Omicron](#), putting it on track to become the third adapted shot by the two companies to be approved in the bloc.

The vaccine, dubbed Comirnaty, is to be used for preventing COVID-19 in adults and children with a dosage-dependent on previous vaccinations.

The European Medicines Agency (EMA) said on Wednesday its Human Medicines Committee (CHMP) had recommended the updated vaccine for children six months through four years of age as part or all of the primary three-dose vaccination series, depending on how many prior doses they had received.

It could be a single dose for those with a history of completion of a COVID-19 primary vaccination course or prior SARS-CoV-2 infection, the committee added.

England Accelerates Vaccine Programs Due to New COVID Variant

Reuters reported:

England will bring forward the start of its autumn [flu](#) and [COVID-19](#) vaccination programs as a precautionary step after the identification of highly mutated COVID variant BA.2.86, which has been found in Britain.

Scientists have said BA.2.86, an offshoot of the [Omicron](#) variant, is [unlikely](#) to cause a devastating wave of severe disease and death, given immune defenses built up worldwide from vaccination and prior infection.

However, Britain's health ministry said annual vaccination programs for older and at-risk groups would start a few weeks earlier than planned in light of the variant.

Certain SSRIs May Increase Arrhythmia Risk in Select Patients — at Recommended Dose in People Over 65, Potentially Pro-Arrhythmic Concentrations Predicted in 20%

MedPage Today reported:

Therapeutic doses of some selective serotonin reuptake inhibitors (SSRIs) may lead to cardiotoxic concentration levels associated with increased risk of arrhythmia in certain groups of patients, including those 65 and up, according to a Norwegian cohort study.

In patients 65 and over taking escitalopram (Lexapro) daily, about 20% were predicted to reach potentially pro-arrhythmic concentrations with a 10-mg dose, which increased to about 60% with a 20-mg dose, reported Erik Sveberg Dietrichs, MD, Ph.D., of the Center for Psychopharmacology at Diakonhjemmet Hospital in Oslo, and co-authors in [eBioMedicine](#).

Cardiac monitoring should be considered for patients who are determined to be at risk of arrhythmia, as should alternative antidepressant treatments, the authors concluded.

Medicare Drug Price Negotiations Could Have Limited Impact at First

Axios reported:

Depending on who you ask, the first-ever Medicare drug negotiations [announced yesterday](#) will either mean huge pocketbook relief for seniors or the demise of America's [pharmaceutical industry](#) — but the immediate impact will likely be relatively small, experts told Axios.

Why it matters: There are still questions about how the [Biden](#) administration will arrive at what it thinks is a fair price for the drugs and how much of the savings from lower prices will ultimately be passed on to seniors.

The big picture: The 10 drugs named by the Biden administration include some that cost Medicare the most money and combined cost \$50 billion last year.

The negotiated prices for the drugs announced yesterday are set to take effect in 2026, but lawsuits from six drugmakers and two allied groups could delay or even prevent the law's implementation.

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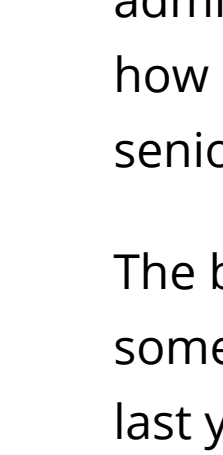
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Leslie Taylor

5 days ago edited

SAVANTS: We don't need wireless technology and here's why. Savants often possess extraordinary knowledge or creative abilities they could not possibly have acquired on the basis of their experience or learning. Some demonstrate psychic abilities - ESP. They are often in other ways mentally or socially impaired. The savant syndrome was popularized in the 1988 movie "Rain Man." Kim Peek, the developmentally disabled man who was the inspiration for the film, knew more than 7,600 books by heart, as well as every area code, highway, zip code, and television station in the U.S. Trivial information yes, but we can learn from how and why it is they seem to automatically, instantly, know things beyond ordinary human knowledge. Faster than your smartphone and without all the bad things that come with them, to say nothing of being transhumanized. I've personally known people with surprising abilities, but not to the extent of savants or in other ways as dysfunctional. Their, along with the rest of us rather typical people, knowing why savants can do what they do is well worth considering.

Also, consider the use of the dream state and ways to overcome insomnia. We need increased intelligence and connection to the Divine spiritual state (thus advanced capabilities), peace of mind and rest if we are to evolve, to survive the current deliberate assaults against, and in other ways imperiled, all of humanity.

In the "Miracles For All" website: <https://miraclesforall.com/>... if you scroll down to read "SAVANTS and WHY IT IS IMPORTANT THAT WE KNOW WHY AND HOW THEY DO WHAT THEY DO" and the following post: CREATIVELY INSPIRING AND OTHER HELPFUL DREAMS AND A CURE FOR INSOMNIA

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